APR 1 8 2001

K010190

510(k) Summary

Trident™ Porous Titanium Acetabular Component

The Trident™ Porous Titanium Acetabular Shells described in this 510(k) submission consist of single use devices which are intended for cemented or cementless fixation within the prepared acetabulum. The Trident™ Porous Titanium Acetabular Shells are intended for mating with the commercially available Trident™ UHMWPE Acetabular Inserts (N_2Vac packaged and Crossfire™ styles), also single use devices.

If supplemental bone screw fixation is deemed necessary, Osteonics® 5.5mm and 6.5mm Cancellous Bone Screws (K894124, K873251) can be placed through the shells' dome screw holes without interfering with the seating of the insert.

The Trident™ Porous Titanium Acetabular Shells are compatible with any appropriately selected, legally marketed Howmedica Osteonics hip stem/head combination.

Indications:

The indications for use of the Trident™ Porous Titanium Acetabular Shell, in keeping with those of other legally marketed Howmedica Osteonics acetabular component systems, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previously unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Contraindications:

As with other Howmedica Osteonics hip replacement acetabular component systems, the contraindications for the Trident™ Porous Titanium Acetabular Component include:

- Any active or suspected latent infection in or about the hip joint.

- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support and fixation of the prosthesis.
- Skeletal immaturity.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Trident™ Porous Titanium Acetabular Component, when used with the commercially available Trident™ UHMWPE Acetabular Insert, is an artificial total hip replacement device which consists of an acetabular shell and a mating insert. Each insert/shell assembly is intended to resurface the acetabulum thereby providing a suitable articulating surface for a mating artificial stem/head combination.

The Trident™ Porous Titanium Acetabular Component is manufactured from ASTM F-136 Ti6Al-4V ELI alloy, and employs a porous coating fabricated from ASTM F-67 Commercially Pure (CP) Titanium.

The Trident™ Porous Titanium Acetabular Shells are characterized by the following features:

- The outer shell has a single radius (hemispherical) geometry, similar to that of the Trident™ Spherical Shell predicate devices.
- A shell substrate composed of titanium alloy (Ti6Al-4V ELI) comparable to that used in other Howmedica Osteonics acetabular components, including the Trident™ predicate shell.
- A titanium porous coating (CP Titanium) which meets the definition of porous coating outlined in 21 CFR 888.3358, and is comparable to that used in other Howmedica Osteonics hip and knee components, as well as the Implex Hedrocel Acetabular component.

- An interior geometry which allows a mating with the Trident™ UHMWPE inserts through maximum conformity and a wireless locking mechanism.
- Availability with screw hole options and cluster screw holes which accept Osteonics® 5.5mm and 6.5mm Cancellous bone Screws (K873251, K894124). A dome hole which is compatible with the optional, currently marketed Osteonics® Acetabular Dome Hole Plugs (K942809). The Osteonics® 5.0mm Cancellous Screws are available for use with peripheral screw holes.
- A range of outer diameters from 40 through 82mm in 2mm increments.
- The following shell configurations will be available:
  - dome hole only, no screw holes
  - 2-3 cluster screw holes, and dome hole
  - 3-5 cluster screw holes and dome hole
  - 5 cluster screw holes with 4 inferior screw holes, and dome hole
  - 8-12 multiple dome screw holes and dome hole
  - 5-7 peripheral screw holes and dome hole

The single radius hemispherical Trident™ Porous Titanium Acetabular Shells provides the acetabular component with intrinsic stability by allowing primary initial fixation through a solid interference fit. The acetabulum is under reamed by 1-2mm to provide initial stabilization.

The Porous Titanium (titanium foam) coating is comprised of a three dimensional open cell structure titanium foam which is fabricated by a proprietary process by sintering commercially pure (CP) titanium beads. This open cell structure is then sintered to the Ti6Al-4V ELI substrate material of the shell. The titanium foam coating conforms to the requirements of 21 CFR §888. 3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

Characterization of the porous coating was presented using the testing outlined in the FDA document "Guidance Document for Testing Orthopaedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement."

The Trident™ Porous Titanium Acetabular Component is substantially equivalent to other legally marketed devices. These products are listed below:

1) Trident™ Spherical Acetabular Shells with PS Coating – K001449
   Howmedica Osteonics Corp.
2) Osteonics MicroStructured® Acetabular Shells – K925883
   Osteonics Corp.
3) Vitalock® Acetabular Shell – K930223
   Howmedica Inc.
4) Acetabular Shells with Mesh Ingrowth Surface – K973163
   Howmedica Inc.
5) Hedrocel® Modular Elliptical Acetabular Component – K001039
   Implex Corporation

A discussion of the equivalent features was presented.

For further information please contact:

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(201) 934-4359

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Ms. Margaret F. Crowe
Howmedica Osteonics
Regulatory Affairs Consultant
59 Route 17
Allendale, New Jersey 07401

Re: K010170
Trade Name: Trident Porous Titanium Acetabular Component
Regulation Number: 888.3358
Regulatory Class: II
Product Code: LPH
Dated: January 17,2001
Received: January 18,2001

Dear Ms. Crowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K010170

Device Name: Trident™ Porous Titanium Acetabular Component

Indications for Use:

The indications for use of the Trident™ Porous Titanium Acetabular Component, in keeping with those of other legally marketed Howmedica Osteonics acetabular component systems, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previously unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010170